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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/058,589	04/10/1998	IAN KIMBER	138.41.US01	7637

26271 7590 10/31/2003
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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/31/2003

39

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/058,589

Applicant(s)

KIMBER ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10,21,23,24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10,21,23,24 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of applicants' amendments and remarks, and the declaration of Dr. Varadhachary is acknowledged.

Claims Rejection 35 U.S.C. – 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10, 21, 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Morinaga Milk Inc. (JP 07-233086), and De Lacharriere et al. (US Patent 5,658,581).

2. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

3. Teng et al. does not teach expressly the treatment of the particular dermal disorder herein or the employment of biological analog or fragments of lactoferrin.

However, Britigan teaches generally that lactoferrin are known to be useful as an anti-inflammatory agent. See, particularly, page 151, the summary and conclusion. Morinaga Milk Inc. teaches that lactoferrin or its derivatives are known to be useful for treating various skin disorders, including allergic dermatitis. See, the abstract. De Lacharriere et al. teach that TNF antagonists, lactoferrin is known to be useful for treating or preventing skin inflammation

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induced by certain cosmetic or pharmaceutical allergen, See, particularly, the abstract, column 3, line 4 bridging column 4, line 39, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis. A person of ordinary skill in the art would have been motivated to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis because lactoferrin is well-known to be useful for anti-inflammation, and is further known particularly useful for treatment of skin inflammation, particularly, allergic dermatitis. Regarding the functional limitation in claim 7, i.e., “a local immune response characterized by increased production of TNF- α ” and in claim 21, “a dermal inflammatory response that is characterized by accumulation of dendritic cell in lymph nodes”, note such limitation is not seen to render the claimed invention any patentable weight since the ultimate method, e.g., administering lactoferrin to person with dermal disorder such as contact dermatitis, UV-induced inflammation, psoriasis, skin aging or diaper rash, is not further limited by such functional language. Further, a method for treatment of a symptom would have been reasonably expected to be effective for the treatment of the symptom despite the underline etiology that causes the symptom. Finally, the optimization of a result effective parameter, e.g., effective amount of therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. As to the newly added limitation “that is exposed to an allergen,” note allergic dermatitis is caused by exposing to allergen.

Response to the Arguments

Rejections set forth in the prior office action, but not repeated herein are withdrawn in view of applicants' amendments, remarks, and the declaration

Applicants' amendments and remarks, and the declaration of Dr. Varadhachary have been fully considered, but are not persuasive with respect to the rejections set forth above.

4. The declaration under 37 CFR 1.132 filed August 21, 2003 is insufficient to overcome the rejection of claims 5-10, 21, 23, 24 and 26-29 based upon Teng et al. in view of Britigan, Morinaga Milk Inc., and De Lacharriere et al. as set forth in the last Office action because of the reasons discussed below.

5. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

6. Applicants' assertion that Morinaga Milk Inc. does not teach or suggest the use of lactoferrin to treat an allergen-induced immune response is in error. Morinaga Milk particularly, teaches the usefulness of lactoferrin for treating allergic dermatitis (see the abstract). In fact, Morinaga Milk expressly discloses the effect of lactoferrin for treating allergic contact dermatitis (see column 6, lines 19-28). Therefore, the cited reference fairly suggests the usefulness of lactoferrin in treating allergic inflammation. Note antimicrobial activity is just one of lactoferrin's known properties, not the only known property.

7. Applicants argue that De Lacharriere does not provide suggestion for one of skilled in the art to select lactoferrin, ... to conduct the test under the particular condition that mammal has

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been inflicted with allergen.” Note De Lacharriere teaches the usefulness of TNF antagonists for preventing cosmetics induced allergic reaction, lactoferrin is one of the several particular compounds used for that purpose. See the claims.

8. For reasons discussed above, the pending claims have been properly rejected.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

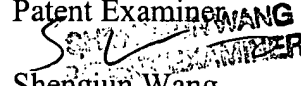
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner **WANG**

Shengjun Wang
October 27, 2003